Regs. package

DATA EVALUATION RECORD

1. Chemical: Simazine
   2-chloro-4,6-bis(ethylamino)-S-triazine

2. Test Material: Simazine Technical 97.6% Active Ingredient

3. Study Type: Freshwater Fish 96-Hour LC_{50}

   Species Tested: *Salmo gairdneri*

4. Study ID: Thompson, C.M.; Forbis, A.D. (1983) Acute Toxicity of Aquazine (Simazine) to Rainbow Trout (*Salmo gairdneri*). Prepared by: Analytical Bio-Chemistry Laboratories, Inc., Columbia, MD. Submitted by: Ciba-Geigy Corporation, Greensboro, North Carolina. ABC Static Bioassay Report No. 30452. EPA Accession No. 265011. MRID 00163135

5. Reviewed By: Thomas M. Armitage
   Fisheries Biologist
   EEB/HED
   Signature: Thomas M. Armitage
   Date: 10-31-86

6. Approved By: Raymond W. Matheny
   Supervisory Biologist
   EEB/HED
   Signature: Raymond W. Matheny
   Date: 10-31-86

7. Conclusions:

The study documents a 96-hour LC_{50} > 10 mg/L for rainbow trout exposed to technical simazine. The study does not, however, fulfill the Guidelines requirement for a freshwater fish LC_{50} determination. This is because a statistically calculated LC_{50} with 95 percent confidence limits is not reported. The slope of the dose-response line should also be calculated and reported. At the highest dose level tested, 10 mg/L, no effect was observed. A statistically calculated LC_{50} need not be reported only if it is demonstrated that a chemical will have an LC_{50} greater than 100 mg/L. This conclusion must be reached by testing at least 30 animals at a concentration of 100 mg/L or greater. Clearly this study design does not fulfill this requirement.

8. Recommendations:

The study must be repeated using dose levels high enough to report a definitive LC_{50} and 95 percent confidence limits. Alternatively, it can be demonstrated that the 96-hour LC_{50} is greater than 100 mg/L. At least 30 test animals must be tested at exposure levels of 100 mg/L or greater.

9. Background:

The study, an acute toxicity determination for coldwater fish species with technical simazine, was submitted to fulfill a data requirement identified in the reregistration guidance package.

10. Discussion of Individual Test: N/A.

11. Materials and Methods: (Definitive Test)

a. Test Animals: Were rainbow trout obtained from Spring Creek Trout Hatchery in Lewistown, Montana. The fish had a mean weight of 1.0 (± 0.25) g and a mean standard length of 40 (± 3.4) mm.

Test System: 5-gallon glass vessels, 15 liters of test solution. Static exposure for 96 hours. Initial pH of 7.2 to 7.6. Day 0 dissolved O_2 of 10.0 mg/L. Test vessels were kept in a water bath at 12.0 °C (± 1.0 °C).

b. Dose: Static bioassay using nominal concentrations; acetone was used as a solvent at 0.5 mL/mL of test water.

c. Design: Ten fish per level. Five dose levels plus solvent and freshwater controls (1.0, 1.8, 3.2, 5.6, and 10.0 mg/L).

d. Statistics: No mortality was observed at the highest dose level. No statistical analysis was required.

12. Reported Results:

The 24-, 48-, and 96-hour LC_{50} values for Aquazine were > 10 mg/L. The highest concentration tested (10 mg/L) produced no mortality or observed adverse effects.

13. Study Authors' Conclusions/QA Measures:

96-hr LC_{50} > 10 mg/L.

"In accordance with ABC Laboratories intent that all studies conducted at our facilities are designed and function in conformance with good laboratory practice regulations and the protocols for individual laboratory studies, an inspection of the final report for Aquazine was conducted and found to be in an acceptable form by a member of our Quality Assurance Unit. An inspection of the daily mortality rate of the test organisms prior to the initiation of the study indicated they were in good health and should not bias the observed mortality in the study. A procedure audit was conducted on protocol #7601 (rainbow trout) on May 9, 1983. A final inspection of all data and records on May 27, 1983 indicated that the report submitted to you is an accurate reflection of the study as it was conducted by ABC Laboratories."

14. Reviewer's Discussion and Interpretation of the Study:

a. Test Procedures: With the following exception, the procedures followed were in accordance with protocols recommended by the Guidelines. A definitive LC_{50} with 95 percent confidence limits was not reported. Unless it can be demonstrated that the LC_{50} is greater than 100 ppm, the LC_{50} and 95 percent confidence limits must be reported. The highest dose level tested, 10 mg/L, is not high enough to demonstrate an $LC_{50} > 100$ mg/L.

b. Statistical Analysis: No mortality was observed. Therefore, no statistical analysis was required.

c. Discussion/Results: The study documents a 96-hour $LC_{50} > 10$ mg/L. The study does not fulfill the requirement for a freshwater fish acute LC_{50} determination because, unless it can be demonstrated by testing 30 or more animals at dose levels of 100 mg/L or higher that the LC_{50} is > 100 mg/L, a definitive LC_{50} and 95 percent confidence limits must be reported.

d. Adequacy of Study:

(1) Classification: Supplemental.

(2) Rationale: See section 7 above.

(3) Reparability: No repair possible. Study must be repeated using higher dose levels.

15. Completion of One-Liner for Study:

One-liner form completed October 21, 1986.

16. CBI Appendix: Data attached.

TABLE 3

Mortality Rates and Water Quality Measurements During the Acute Toxicity Test of Aquazine® to Rainbow Trout (Salmo gairdneri)

mg/l Concentration	Percent Mortality Hours			Water Quality								
				0 hours			48 hours			96 hours		
	24	48	96	Temp. °C	D.O.[a] mg/l	pH[b]	Temp. °C	D.O. mg/l	pH	Temp. °C	D.O. mg/l	pH
Control	0	0	0	12	10.0	7.4	12	8.5	7.1	12	8.4	7.1
Solvent Control	0	0	0									
1.0	0	0	0	12	10.2	7.6	12	8.5	7.2	12	8.2	7.2
1.8	0	0	0									
3.2	0	0	0	12	10.2	7.6						
5.6	0	0	0									
10	0	0	0	12	10.3	7.7	12	8.6	7.2	12	8.1	7.2

[a]Dissolved oxygen concentrations - Dissolved Oxygen Probe (YSI Model 54).

[b]pH - pH Probe (Corning Model 476182) used with a Corning Model 125 pH and mV meter.

NOTE: Dissolved oxygen saturation at the test temperature of 12°C is 10.8 mg/l.

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CASE: GS0070 SIMAZINE FRSTR

CONT-CAT: 01 GUIDELINES: 72-1

MRID: 163135

Thompson, C.; Forbis, A. (1983) Acute Toxicity of Aquazine (Simazine) to Rainbow Trout (Salmo gairdneri): Static Bioassay Rept. #30452. Unpublished study prepared by Analytical Bio-Chemistry Laboratories, Inc. 14 p.

REVIEW RESULTS:

VALID ✓ INVALID _____ INCOMPLETE _____

GUIDELINE: SATISFIED ___ PARTIALLY SATISFIED _____ NOT SATISFIED ✓

DIRECT RVW TIME = START DATE: END DATE:

REVIEWED BY: Les Touart

TITLE: Fisheries Biologist

ORG: EEB/EFED H7507C

LOC/TEL: 557-2438

SIGNATURE: L Touart DATE: 3-C-89

APPROVED BY:

TITLE:

ORG:

LOC/TEL:

SIGNATURE: DATE: